

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 7-2005)

ATTORNEY'S DOCKET NUMBER

930008-2209 (BOE0004US.NP)

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/577,569

INTERNATIONAL APPLICATION NO.  
PCT/EPO04/12230

INTERNATIONAL FILING DATE  
October 28, 2004

PRIORITY DATE CLAIMED  
October 31, 2003

TITLE OF INVENTION

Pharmaceutical Active-Ingredient-Containing Formulation with Coating

APPLICANT(S) FOR DO/EO/US

Klokkers et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EM 054665613US

U.S. APPLICATION NO (if known, see 37 CFR 1.5) <div style="text-align: center;"><b>10/577,569</b></div>	INTERNATIONAL APPLICATION NO. <div style="text-align: center;"><b>PCT/EPO04/12230</b></div>	ATTORNEY'S DOCKET NUMBER <div style="text-align: center;"><b>930008-2209 (BOE0004US.NP)</b></div>													
23. Other items or information: 1) Copy of Notification of Missing Requirements; and 2) Petition Under 37 CFR 1.47(a);															
The following fees have been submitted:		CALCULATIONS	PTO USE												
24. <input type="checkbox"/> Basic national fee ..... \$300	\$	\$0.00													
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 All other situations. .... \$200	\$	\$0.00													
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. .... \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. .... \$400 All other situations. .... \$500	\$	\$0.00													
<b>TOTAL OF 24, 25 and 26 =</b>		\$	\$0.00												
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.															
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Total Sheets</td> <td style="width: 15%;">Extra Sheets</td> <td style="width: 35%;">Number of each additional 50 or fraction thereof (round up to a whole)</td> <td style="width: 35%;">RATE</td> </tr> <tr> <td style="text-align: center;">- 100 =</td> <td style="text-align: center;">0 /50 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$250.00</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	- 100 =	0 /50 =	0	x \$250.00	\$	\$0.00					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE												
- 100 =	0 /50 =	0	x \$250.00												
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$	\$130.00												
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">CLAIMS</td> <td style="width: 15%;">NUMBER FILED</td> <td style="width: 35%;">NUMBER EXTRA</td> <td style="width: 35%;">RATE</td> </tr> <tr> <td>Total claims</td> <td style="text-align: center;">- 20 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td style="text-align: center;">- 3 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$200.00</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	- 20 =	0	x \$50.00	Independent claims	- 3 =	0	x \$200.00	\$	\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE												
Total claims	- 20 =	0	x \$50.00												
Independent claims	- 3 =	0	x \$200.00												
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00		\$	\$0.00												
<b>TOTAL OF ABOVE CALCULATIONS =</b>		\$	\$130.00												
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$	\$0.00												
<div style="text-align: right; font-weight: bold; font-size: 1.2em;">Petition fee</div>		\$	\$130.00												
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$	\$0.00												
<b>TOTAL NATIONAL FEE =</b>		\$	\$130.00												
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$	\$0.00												
<b>TOTAL FEES ENCLOSED =</b>		\$	\$260.00												
01 FC:1617 130.00 OP 02 FC:1618 130.00 OP		Amount to be	\$												
		Amount to be	\$												

02/23/2007  
01 FC:1617  
02 FC:1618

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1619. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
Telephone: (856) 810-1515  
Facsimile: (856) 810-1454

Jane Massey Licata  
SIGNATURE

Jane Massey Licata

NAME

32,257

REGISTRATION NUMBER

February 21, 2007

DATE



02/22/07

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.

10/577,569

FIRST NAMED APPLICANT

FROMMER, LAWRENCE  
& HAUG, LLP

Karin Klokke

ATTY. DOCKET NO.

930008-2208

INTERNATIONAL APPLICATION NO.

PCT/EP04/12230

I.A. FILING DATE

10/28/2004

PRIORITY DATE

10/31/2003

Ronald R. Santucci  
Frommer Lawrence & Haug  
745 Fifth Avenue  
New York, NY 10151

Docket System  
Status Report  
Docket Book

CONFIRMATION NO. 6210

371 FORMALITIES LETTER



\*OC000000021674468\*

DOCKETED

Date Mailed: 12/21/2006

2-21-07  
7-21-07

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 04/27/2006
- English Translation of the IA filed on 04/27/2006
- Copy of the International Search Report filed on 04/27/2006
- Copy of IPE Report filed on 04/27/2006
- Preliminary Amendments filed on 04/27/2006
- Information Disclosure Statements filed on 04/27/2006
- Oath or Declaration filed on 04/27/2006
- U.S. Basic National Fees filed on 04/27/2006
- Priority Documents filed on 04/27/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/577,569	PCT/EP04/12230	930008-2208

**BOETERS & LIECK** - PATENTANWÄLTE  
- EUROPEAN PATENT AND  
- TRADEMARK ATTORNEYS

FACSIMILE: 001-856-810-1454  
Licata & Tyrrell P.C.  
Attn.: Ms Jane Massey Licata  
66 E. Main Street  
Marlton, New Jersey 08053  
USA

Dist. Ing. 4 Peter Fieck  
 Dist. Chem. Dr. Hans D. Bockert  
 Dist. Ing. 3 Bert Bauer (-2002)  
 Dist. Ing. 3 Othmar Fausch  
 Dist. Chem. Dr. Dietmar G. Fiedler  
 Dist. Ing. Roland Veith

February 20, 2007/St  
via facsimile

TECHNOLOGY

**URGENT**

Your ref.: unknown  
Our ref.: 16508  
US Patent Application No. 10/577 569  
Hexal AG

$\lambda = 0.0001$   
 100 iterations  
 10000 iterations  
 100000 iterations  
 1000000 iterations  
 10000000 iterations

Dear Ms Massey Licata:

On February 12, 2007, Frommer Lawrence & Haug LLP transferred the above file to your firm. Tomorrow, February 21, 2007, is the deadline date for filing the response to missing requirements. Enclosed please find the following documents

- declaration
- assignment

signed by three inventors. The fourth inventor, Mr. Thomas Rillmann, refuses to sign said documents. Further, said declaration cites the Frommer et al. address as address for correspondence. Please advise whether this will be acceptable to the USPTO or let us have your suggestions how to handle the situation via return facsimile.

Thank you very much for your assistance.

Very truly yours,

Dieter Forstmeier  
(Dr. Forstmeier)

Encls.  
a/m